PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Appl. No.	:	10/021,622
Applicant(s)	:	Paul F. Laeseke et al.
Filed	:	December 12, 2001
Title	:	Cauterizing Biopsy System
TC/A.U.	:	3736
Examiner	:	Charles A. Marmor, II
Docket No.:	:	1512.211

APPELLANT'S REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer dated October 3, 2007, Appellant provides this Appellant's Reply Brief. Appellant believes this Reply Brief to be in full conformance with 37 CFR §41.41, and as such, entry of this Brief is respectfully requested. Please charge any additional fees required to Deposit Account No. 50-1170.

I. REAL PARTY IN INTEREST

The present application is assigned to the Wisconsin Alumni Research Foundation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 5 – 8 and 10 are currently pending in the subject patent application and stand finally rejected. Claims 1 – 4, 9, and 11 – 20 have been withdrawn from consideration. Claims 5-8 and 10 are currently on appeal.

IV. STATUS OF AMENDMENTS

In response to a final office action, an amendment was filed on July 18, 2005. In an advisory action dated October 14, 2005, the amendments were denied entry as raising new issues. Accordingly the claims have reverted to their status as all of the date of the final rejection all of May 17, 2005.

V. CLAIMS 5-8

The citations in the following section refer to paragraph numbers of the published application.

Claim 5 is an independent apparatus claim that recites a biopsy needle assembly comprising an introducer shaft (12) sized for percutaneous insertion into a patient along an insertion path (56) to locate a conductive surface (58) at the second end (20) at a biopsy site (34). A cauterizing electrical source is connected to the second end (22) which communicates with tissue (34) at the conductive surface (58) by means of insulating conductor (18) to heat that tissue (34). A biopsy needle (36) interfits with the introducer shaft (12) and is guided thereby. The biopsy needle includes a sampling means (40) for removal of a tissue sample (42) before

cauterization of the insertion path (56) using the electrically conductive surface (14). *Specification: paragraphs [0027]-[0040].*

Claim 6 is an apparatus claim dependent on claim 1, which recites that the electrically conductive stylet (58) has a rounded tip. *Specification: paragraphs 38-40.*

Claim 7 is an apparatus claim dependent on claim 1, which recites that the introducer shaft (12) is a hollow tube (14) having an outer conductive covering (30) and wherein the insulated conductor is provided by a portion of the conductive stylet (58) fitting within the hollow tube (14). *Specification: paragraphs [0038]-[0040].*

Claim 8 is an apparatus claim dependent on claim 5, which recites the insulating covering (63) over a portion of the shaft of the conductive stylet to provide the insulated conductor. *Specification: paragraphs 38-40.*

Claim 10 is an independent claim including all of the elements of claim 1 except for the stylet and instead reciting a temperature sensor (60) positioned at the electrically conductive surface. *Specification: paragraph 40.*

VII. ARGUMENT

In the Examiner's Answer dated October 3, 2007, the Examiner misconstrues the language of claim 5 in several ways. First, the Examiner states that because the device recited in Roberts may be used to gain access to the bile ducts of a patient, it necessarily follows that the device recited in Roberts may be "sized for percutaneous insertion." In support for this argument, the Examiner states that because bile duct vessels are much smaller in diameter than that of the small intestine, it must follow that the device must be small enough to fit into smaller vessels, and therefore the endoscope system of Roberts may be sized for percutaneous insertion.

The Examiner's characterization of the term "sized for percutaneous insertion" fails to appreciate that this term is a limitation of both size and structure. The endoscope recited in Roberts is simply not capable of use as recited in claim 5 in any size because it is simply too large, too flexible and too blunt to be used for percutaneous insertion as the term in used in the present application. To accept the Examiner's definition of "sized for percutaneous insertion," any object which may be made sufficiently small enough may then be sized for percutaneous insertion regardless of whether it is actually capable of being inserted through a person's skin. Accordingly, for at least the reasons stated above, Roberts fails to recite an introducer shaft sized for percutaneous insertion.

Second, the Examiner's argument that the sheath 12 of Roberts constitutes a stylet is incorrect in light of the definition given to the term by the present application. During prosecution, the words of a claim must be given their plain meaning unless such meaning is inconsistent with the specification. *See* MPEP §2111.01 (I). As defined in the present application, the term stylet is defined as a "sharp rod." *Specification: paragraph [0004].*

In the Examiner's Answer, the Examiner relies on two separate dictionary definitions for the term "stylet," both from the Merriam-Webster Online Dictionary. As defined therein, a stylet is a "slender medical probe" or a "thin wire inserted into a catheter to maintain rigidity or into a hollow needle to maintain patency." The definitions cited by the Examiner in the Answer are inconsistent with the manner in which the term is used in the specification. Accordingly, the Examiner's reliance on those definitions is improper.

Assuming, *arguendo*, that it is necessary to resort to a dictionary definition for the term stylet, a more appropriate definition of the term would be that of "a stiletto or dagger" or "any similar sharp pointed instrument" from Webster's New Universal Unabridged Dictionary, Barnes

& Noble, 1996 as the present invention is directed to a device for percutaneous insertion and therefore inherently requires the use of a sharp pointed instrument in order to pierce the skin. In addition, the Merriam-Webster Online Dictionary relied upon by the Examiner provides other definitions of the term stylet, which the Examiner chooses to ignore. Namely, the Merriam-Webster Online Dictionary also defines a stylet as "a pointed instrument" or "stiletto." As the present invention is directed to a biopsy needle, it follows that the term stylet should be directed to a definition more suitable thereto.

Finally, the sheath 12 recited in Roberts does not meet the above-referenced definitions for a stylet as used in the present application (i.e., a sharp rod) or as known to those of ordinary skill in the art (i.e., stiletto or dagger or any similar sharp pointed instrument). Rather, sheath 12 is configured to serve as a covering to a resecting device. As such, Roberts fails to recite the limitation of a stylet as recited in claim 5, and therefore, the Examiner's rejection is improper.

Third, the Examiner's argument with respect to the claim limitation "cauterization of the insertion path" defies the plain and ordinary meaning of the language of claim 5. The Examiner argues that "[t]he current claim language does not disclose the cauterization of the entire insertion path of the biopsy assembly, but instead can be interpreted as cauterizing the biopsy site at a particular location along the insertion path." Examiner's Ans. § 10, ¶ 5.

As noted previously, claim language is to be given its plain meaning unless it is inconsistent with the specification. Further, the plain meaning refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art. MPEP § 2111.01 (III). As is understood to those skilled in the art and stated in the specification, "cauterization of the insertion path" is understood to be the cauterization of a region along the insertion path. In

addition, the specification states that withdrawing the introducer needle "produc[es] a cauterization region 54 along the biopsy track 56." Specification: *paragraph [0037]*.

The Examiner's argument that the claim language may be interpreted as cauterizing the biopsy site at a particular location along the insertion path is contrary to the plain and ordinary meaning of the recited limitation. As noted previously, the specification recites the cauterization of a cauterization region 54 that is along the biopsy track 56, whereas Roberts discloses the cauterization of the biopsy site itself to prevent blood loss, not the insertion path of the endoscope. As such, Roberts fails to recite the cauterization of the insertion path" as is required by the plain and ordinary meaning of claim 5. Accordingly, Roberts fails to recite the claim limitation of "cauterization of the insertion path."

Finally, the Examiner improperly states that the electrically conductive surface of claim 5 does not have to be disposed directly on the introducer itself. Claim 5 clearly recites a first end of the introducer shaft wherein "the first end [has] an electrically conductive surface . . . . " Accordingly, the current claim language of claim 5 necessarily requires that the electrically conductive surface be included on the first end of the introducer shaft contrary to the Examiner's statement. As the Roberts reference fails to teach an introducer shaft having an electrically conductive surface, the Examiner's rejection of claim 5 is improper.

For the reasons stated above and those recited in Appellant's Second Revised Brief on Appeal, the Examiner's rejections of claims 5-8 and 10 are improper.

VIII. CONCLUSION

Claim 5 stands rejected under 35 U.S.C. §102(e) as anticipated by Roberts. Claims 5 – 8 and 10 stand rejected under 35 U.S.C. §103 as unpatentable over Roberts in combination with Lennox.

The rejection under 35 U.S.C. §102(e) is improper because Roberts fails to disclose all of the elements recited in claim 5. The rejection under 35 U.S.C. §103 is improper because the cited references fail to disclose all of the elements of the claims, and further because no proper motivation to combine these references has been shown. Therefore, the Appellants respectfully request that the rejection of claims 5 – 8 and 10 be reversed.

Respectfully submitted,

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Dated: November 19, 2007

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CLAIMS APPENDIX

1-4. (Canceled)

5. (Previously Presented) A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

wherein the electrically conductive surface is a conductive stylet having a first end supported by the introducer shaft.

6. (Original) The biopsy needle assembly of claim 5 wherein the conductive stylet has a rounded tip.

7. (Previously Presented) The biopsy needle assembly of claim 5 wherein the introducer shaft is a hollow tube and wherein the insulated conductor is provided by a portion of the conductive stylet fitting within the hollow tube.

8. (Original) The biopsy needle assembly of claim 5 wherein a shaft portion of the conductive stylet includes an outer insulating covering to provide the insulated conductor.

9. (Canceled)

10. (Previously Presented) A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

further including a temperature sensor positioned at the electrically conductive surface.

11-20. (Canceled)

EVIDENCE APPENDIX

No additional evidence is being presented.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.